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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,595

02/23/2007

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SPEI3003/ESS

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EXAMINER

YU, HONG

ART UNIT

PAPER NUMBER

1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,595	Applicant(s) SPEIRS ET AL.	
	Examiner HONG YU	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,7-11,14,18,20,24-26,28-30,32,33 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,7-11,14,18,20,24-26,28-30,32,33 and 40-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

The amendment file on 12/17/2009 is acknowledged. Claims 1, 3-6, 12, 13, 15-17, 19, 21-23, 27, 31, and 34-39 have previously been canceled and new claims 42-46 have been added. Claims 2, 7-11, 14, 18, 20, 24-26, 28-30, 32, 33 and 40-46 are under examination in the instant office action.

New ground of rejections necessitated by Applicant's amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-10, 14, 18, 20, 24, 26, 28-30, 32, 40-42, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021).

Applicant's claims

Applicants claim a process for producing particles comprising the steps of; a) admixing water with a component composition comprising at least a rheology modifying agent to produce a paste; b) extrude at least a portion of the paste to form extrudate; c) spheronizing at least a portion of the extrudate to form spheronized particles; and d) drying at least a portion of the spheronized particle; wherein the amount of water added in step a) is controlled so as to provide said spheronized particles in step d) having a particle size distribution such that from about 80% to about 98% , 90 to 98%, and 95 to 98% of the particles have a diameter from about 800 to about 1500 μm (see claims 40, 45, and 46).

Claim 7 recites the said dry particles produced in the said step d) are screened to obtain diameter with the range of about 800 to about 1500 μm .

Claims 8-10, 14, 24, 26, 28-30, 32, 41 recite the said component composition of step a) consisting essentially of from more than 0 to about 90% by weight of the component composition of prednisolone, from about 30 to about 50% by weight of the component composition of a sugar, from about 35 to about 45% by weight of the component composition of microcrystalline cellulose as a cellulose.

Claims 18, 20, and 42 recite the said component comprising at least 5% by weight of component composition of croscarmellose sodium as a rheology modifying agent.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

Speirs teaches a preparation of pellets comprising: a) mixing water with component composition to form a paste; b) extruding the formed paste to form extrudate; c) spheronizing the extrudate; d) drying the sphere pellets (column 5, line 1-8). Speirs further teaches the component composition consisting essentially of (column 4, line 61-65) 5 to 20% by weight of prednisolone (column 4, line 58-60), 10 to 30% by weight of croscarmellose sodium (column 4, line 48-57 and example 10), 40% by weight of microcrystalline cellulose (example 1), and 50% by weight of lactose (example 1), wherein the diameter of the particles are is in the range of 1000 to 1400 μm (example 1).

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Speirs does not teach from about 80% to about 98%, from 90 to 98%, and from 95 to 98% of dried pellets having a diameter from about 800 to about 1500 μm ; but teaches the pellets having a diameter in the range 1000-1400 μm .

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

A prima facie case of obviousness typically exists when the size distribution of claimed pellets overlaps the size distribution of pellets disclosed in the prior art, such as in the instant rejection. MPEP 2144.05. It would have been customary for an artisan of ordinary skill to determine the optimal parameters of extrusion in order to obtain the

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desired pellets size distribution. Thus, absent some demonstration of unexpected results from the choice of extrusion parameters, obtaining a size distribution of from about 80% to about 98%, from 90 to 98%, and from 95 to 98% of dried pellets having a diameter from about 800 to about 1500 μm would have been obvious at the time of Applicants' invention.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021), and further in view of Enders et al. (EP 0 202 409 A2).

Applicant's claims

Applicants claim the amount of water admixed in said step a) being from about 180 to about 190% by weight of the component composition (see claim 2).

***Determination of the Scope and Content of the Prior Art
(MPEP 2141.01)***

The teachings of Speirs are discussed above and applied in the same manner.

***Ascertainment of the Difference between Scope of the Prior Art and the Claims
MPEP 2141.02)***

Speirs does not teach the amount of water in the preparation being from 180% to about 190% by weight of component composition (from 180% to about 190% by weight of component composition is calculated to be from 64.3 to 65.5% by weight of total weight including water).

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This deficiency is cured by Enders et al. who teaches the amount of water in a process of making pellets through extruding being from 35 to 60% by weight of total weight including water (column 2, line 29).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

The amount of water in a process of making pellets through extruding is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of water in a process of making pellets through extruding in order to best achieve the desired results such as the consistency and viscosity of the paste thus affect the size distribution of pellets. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of amount of water in a process of making pellets through extruding would have been obvious at the time of Applicants' invention. MPEP 2144.05.

Claims 11, 33, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021), and further in view of Mulye (US 2004/0224017 A1 with effective filing date of 03/14/2003).

Applicant's claims

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Applicants claim the said component composition of step a) consisting essentially of metronidazole, a rheology modifying agent, a sugar, and a cellulose (see claims 11 and 33).

Claims 43 and 44 recite the said component composition of step a) consisting essentially of paracetamol, a rheology modifying agent, a sugar, and a cellulose.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of Speirs are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Speirs does not teach: i) the said component composition of step a) consisting essentially of metronidazole, a rheology modifying agent, a sugar, and a cellulose; ii) the said component composition of step a) consisting essentially of paracetamol, a rheology modifying agent, a sugar, and a cellulose; but teaches the said component composition of step a) consisting essentially of prednisolone, a rheology modifying agent, a sugar, and a cellulose (column 4, line 61-65).

This deficiency is cured by Mulye who teaches prednisolone, metronidazole, and paracetamol are equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying (paragraph 39 and example 9).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

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It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Speirs and Mulye to substitute prednisolone with metronidazole or paracetamol as an active agent in the composition disclosed by Speirs. Prednisolone, metronidazole, and paracetamol being equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying was well known to a person of ordinary skill in the art at the time of the invention. The motivation for substituting prednisolone with metronidazole or paracetamol as an active agent flows from prednisolone, metronidazole, and paracetamol having been used as equivalent active agents in a preparation comprising mixing, extruding, spheronizing, and drying in the prior art. As shown by the recited teachings, instant claims are no more than substituting prednisolone with its equivalent such as metronidazole or paracetamol. It therefore follows that the instant claims define prima facie obvious subject matter.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021), and further in view of Wolozin (US 6,472,421 B1)

Applicants claim the said sugar being lactose monohydrate (see claim 25).

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of Speirs are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

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Speirs does not teach the said sugar being lactose monohydrate, but teaches the said sugar being lactose.

This deficiency is cured by Wolozin who teaches that lactose can be lactose monohydrate and lactose anhydrous (column 9, line 40 and 41).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP 2142-2143)

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Speirs and Wolozin to specify lactose monohydrate as the lactose in the composition disclosed by Speirs. Monohydrate and lactose anhydrous were well known as two types of lactose in pharmaceutical compositions to a person of ordinary skill in the art at the time of the invention. The motivation for specifying lactose being monohydrate lactose flows from monohydrate lactose having been one of the two types of lactose and having being used in the composition taught by Wolozin. As shown by the recited teachings, instant claims are no more than specifying a conventional type of lactose. It therefore follows that the instant claims define prima facie obvious subject matter.

Response to Arguments

Applicant's arguments, filed on 12/17/2009, have been fully considered but they are moot in view of new ground of rejections.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Yu whose telephone number is 571-270-1328. The examiner can normally be reached 8:50-5:20 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./

Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616